UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

In re: WELLBUTRIN XL ANTITRUST LITIGATION	)	Case No. 2:08-cv-2433 (indirect)
	)	Hon. Mary A. McLaughlin

SECOND AMENDED CONSOLIDATED CLASS ACTION COMPLAINT AND JURY DEMAND FOR END PAYORS

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Plaintiffs, Plumbers and Pipefitters Local 572 Health and Welfare Fund, IBEW-NECA Local 505 Health and Welfare Plan, Painters District Council No. 30 Health and Welfare Fund, and Aetna Health of California Inc. (collectively "Plaintiffs"), on behalf of themselves and all others similarly situated, for this Consolidated Class Action Complaint against Defendants Biovail Corporation, Biovail Laboratories, Inc., Biovail Laboratories International SRL (collectively "Biovail"), and SmithKline Beecham d/b/a GlaxoSmithKline ("GSK") (collectively "Defendants"), allege as follows based on personal knowledge, the investigation of their counsel, the review of pleadings and court orders in patent infringement and other litigation concerning the conduct at issue in this action, and information and belief:

I. NATURE OF THE ACTIONS

1. This is an antitrust class action seeking treble damages for Defendants' unlawful exclusion of generics from the market for bupropion HCl extended release, a prescription antidepressant marketed under the brand name Wellbutrin XL. Annual sales of Wellbutrin XL during the Class Period exceeded $1.8 billion, making it one of the top selling drugs in the country. As explained below, Defendants engaged in sham litigation and petitioning, and entered into anticompetitive agreements to improperly maintain monopoly profits in the bupropion hydrochloride extended release market to the detriment of Plaintiffs and a Class of Wellbutrin XL End Payors.

2. Generic versions of brand name drugs contain the same active ingredient, and have been found by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between brand name drugs and generics is price. Generics typically cost at least 30% less than their brand counterparts when there is a single generic competitor, and as much as 80% less when there are multiple generic competitors on the market. As a result, generics constitute both an opportunity for drug purchasers and consumers to obtain enormous

savings, and a threat to the monopoly power and profits of the brand name drug facing generic competition. Generics typically take 90% of the sales from the brand name manufacturer within one year of entry.

3. Acutely aware of these economic realities, Defendants embarked on a scheme to maintain the monopoly profits generated by their control of the bupropion hydrochloride extended release market, and eliminate the threat of competition from cost-effective generic substitutes. This scheme involved at least three key facets.

4. *First*, after four generic pharmaceutical manufacturers, Anchen Pharmaceuticals, Inc. ("Anchen"), Abrika Pharmaceuticals, Inc. ("Abrika"), Impax Laboratories, Inc. ("Impax") and Watson Pharmaceuticals, Inc. ("Watson"), sought approval to sell generic versions of Wellbutrin XL, Defendants, individually or in concert, commenced baseless patent infringement actions against them. These actions were objectively baseless because no reasonable litigant could have realistically expected success on the merits. Defendants commenced these actions solely for the purpose of preventing lower-priced generic bupropion hydrochloride extended release from reaching the market and maintaining their monopoly in this market. *But for the commencement of these actions, generic bupropion hydrochloride extended release would have reached the market no later than November 14, 2005.*

5. Defendants' infringement actions were rejected by each of the courts in which they were brought. In the three cases where patent claim construction hearings were held, three different District Court judges, in three separate Courts, held that the patent claims Defendants asserted were construed in a manner that foreshadowed findings of non-infringement.

6. Moreover, in the only action that reached summary judgment (rather than disposition by settlement), the Court entered summary judgment for the generic competitor, *ruling that the proposed generic formulations did not infringe any Wellbutrin XL patent.*

7. *Second*, on December 20, 2005, in anticipation of defeat in its baseless litigation against generic competitors, Biovail submitted a citizen petition to the Food and Drug Administration ("FDA") seeking an order that would have required its generic competitors to perform additional studies beyond those previously submitted to prove bioequivalence. This citizen petition, like the infringement lawsuits, was objectively baseless and filed for the sole purpose of further delaying market entry of generic substitutes.

8. Biovail's baseless citizen petition delayed the FDA's approval of Anchen's Abbreviated New Drug Application ("ANDA") until December 14, 2006, four months beyond the judgment Anchen received denying Biovail's citizen petition and permitting Anchen to market its generic product. In ruling on the citizen petition, the FDA condemned Biovail's citizen petition filing, stating that the brand manufacturers did not have "the right to be free of generic competition" once their patents had been held unenforceable, and that under these circumstances, "Biovail [should] not be permitted to shield its market share."

9. According to an analysis reported to the FDA by United States Senators Debbie Stabenow (D-Mich.) and Trent Lott (R.-Miss.), the delay in approval of generic bupropion hydrochloride extended release that resulted from the filing of the citizen petition cost consumers $37 million per month. Defendants benefitted from these overpayments at the expense of Plaintiffs and other payors.

10. *Third*, Biovail exacerbated the effects of Defendants' sham litigation and petitioning activities by entering into agreements with the generic manufacturers that further delayed generic entry by some generic manufacturers on some dosage strengths.

11. As a result of Defendants' anticompetitive conduct in the bupropion HCl extended release market, those who paid for bupropion hydrochloride extended release drugs were denied the benefits of free and unrestrained competition. More specifically, Plaintiffs and the End Payor Class were denied the opportunity to choose between brand name Wellbutrin XL and lower-priced generic versions, were forced to pay supra-competitive prices for bupropion hydrochloride extended release.

II. JURISDICTION AND VENUE

12. This Court has jurisdiction over these actions pursuant to the Class Action Fairness Act of 2005 ("CAFA"), 28 U.S.C. §1711, *et seq.*, which vests federal district courts with original jurisdiction over any multi-state class action where the aggregate amount in controversy exceeds $5,000,000 and the citizenship of any member of the class of plaintiffs is different from any defendant. The diversity and amount in controversy requirements of CAFA are satisfied in these consolidated cases.

13. Defendants transact business within this District, and they carry out trade and commerce, in substantial part, in this District. Venue, therefore, is appropriate within this District under 28 U.S.C. §1391(a) and (c). Venue is also appropriate with respect to Defendants Biovail Corporation, Biovail Laboratories, Inc., and Biovail Laboratories International SRL under 28 U.S.C. §1391(d).

III. THE PARTIES

A. Plaintiffs

14. Plumbers and Pipefitters Local 572 Health and Welfare Fund ("Local 572") is a trust fund administered pursuant to the requirements of the Taft-Hartley Act, 29 U.S.C. §186, by an equal number of trustees appointed by labor representatives and union representatives. Local 572 is an "employee welfare benefit plan" and "employee benefit plan" maintained pursuant to §302(c)(5) of the Labor Management Relations Act ("LMRA"), 29 U.S.C. §186(c)(5), and is defined by §§1002(1) and (3) of the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. §1001, *et seq.* As such, Local 572 is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. §1132(d). Local 572's office is located in Davidson County, Tennessee. During the Class Period, Local 572 paid retail pharmacies for bupropion hydrochloride extended release prescriptions filled by its members residing in Tennessee and was injured as a result of Defendants' misconduct.

15. IBEW-NECA Local 505 Health and Welfare Plan ("Local 505") is a trust fund administered pursuant to the requirements of the Taft-Hartley Act, 29 U.S.C. §186, by an equal number of trustees appointed by labor representatives and union representatives. Local 505 is an "employee welfare benefit plan" and "employee benefit plan" maintained pursuant to §302(c)(5) of the Labor Management Relations Act ("LMRA"), 29 U.S.C. §186(c)(5), and as defined by §§ 1002(1) and (3) of the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. §1001, *et seq.* As such, Local 505 is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. §1132(d). Local 505's office is located in Mobile, Alabama. During the Class Period, Local 505 paid retail pharmacies for bupropion hydrochloride extended release prescriptions filled by its members residing in Alabama, New York, New Jersey, and Florida, and was injured as a result of Defendants' misconduct.

16. Painters District Council No. 30 Health & Welfare Fund (D&C 30") is located in Aurora, Illinois and is an "employee welfare benefit plan" and an "employee benefit plan" within the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. §§ 1002(1), 1002(3) and 1003(a). As such, D&C 30 is a legal entity entitled to bring suit in its own name pursuant to 20 U.S.C. § 1132(d). D&C 30 is a not-for-profit trust, sponsored by and administered by a Board of Trustees, established and maintained to provide comprehensive health care benefits to participant-workers who are employed under various collective bargaining agreements and to their dependents. D&C 30 provides comprehensive health coverage for participants and beneficiaries. During the Class Period, D&C 30 paid retail pharmacies for bupropion hydrochloride extended release prescriptions filled by its members and was injured as a result of Defendants' misconduct.

17. Plaintiff Aetna Health of California Inc. ("Aetna") is a California corporation, with its principal place of business in California. Aetna is a health benefit company. During the Class Period, Aetna paid retail pharmacies for bupropion hydrochloride extended release prescriptions filled by its members residing in California and was injured as a result of Defendants' misconduct.

B. Defendants

18. Biovail Corporation is a corporation headquartered at 7150 Mississauga Road, Mississauga, Ontario, Canada. Biovail Corporation is engaged in the development, manufacture, and sale of pharmaceutical products. Biovail Corporation is the largest pharmaceutical manufacturer in Canada. Biovail Corporation's products were distributed in the United States during the Class Period by its wholly-owned United States subsidiaries, by its specialty pharmaceutical product sales force, and through joint ventures and agreements with United States pharmaceutical manufacturers including GSK, AstraZeneca Pharmaceuticals, Wyeth,

Aventis, and others. Biovail Corporation's shares trade on the New York and Toronto Stock Exchanges.

19. Biovail Corporation has at least three wholly-owned United States subsidiaries: Biovail Pharmaceuticals, Inc., Biovail Technologies Ltd. and Pharma Pass Inc. d/b/a Pharma Pass LLC and Pharma Pass Limited. Biovail Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business at 700 Route 202/206, North Bridgewater, NJ 08807. Biovail Pharmaceuticals, Inc. carries out the business of Biovail Corporation in the United States particularly with respect to administrative matters, product distribution, and regulatory functions. Biovail Technologies Ltd is a Delaware Corporation located at 3701 Concorde Parkway, Chantilly, VA 20151. Biovail Technologies Ltd is in the business of manufacturing pharmaceutical preparations and syrups, and medical instruments. Pharma Pass Inc. d/b/a Pharma Pass LLC and d/b/a Pharma Pass Limited is a corporation with its principal place of business at 68 Discovery, Irvine California 92618. Pharma Pass Inc. is in the business of developing advanced oral controlled release technologies and formulations for pharmaceutical applications.

20. Biovail Laboratories, Inc. is a corporation organized and existing under the laws of Barbados, with offices at 100 Chelston Park, Bldg. 2, Collymore Rock, St. Michael, Barbados.

21. Biovail Laboratories International SRL is a corporation organized and existing under the laws of Barbados, with offices at 100 Chelston Park, Bldg. 2, Collymore Rock, St. Michael, Barbados. Biovail Laboratories International SRL holds the intellectual property that underlies Biovail's Corporation's products, and performs all of the activities that are involved with owning the intellectual property portfolio. Biovail Laboratories International SRL develops, manufactures, and sells Biovail Corporation's pharmaceutical products; it licenses its

intellectual property; and it performs strategic planning and decision-making. Biovail Laboratories International SRL owns and operates two manufacturing facilities in Puerto Rico. Defendant Biovail Laboratories International SRL is a successor company to Biovail Laboratories, Inc. and is jointly and severally liable for any harm resulting from its misconduct.

22. SmithKline Beecham Corporation is a Delaware Corporation with its principal offices located at One Franklin Plaza, Philadelphia, Pennsylvania. SmithKline Beecham also conducts business in the name of GlaxoSmithKline ("GSK"), and is a subsidiary of GlaxoSmithKline plc.

23. Defendants' actions are part of, and in furtherance of, the illegal monopolization alleged herein, and were authorized, ordered, or done by Defendants' officers, agents, employees, or representatives while actively engaged in the management of Defendants' affairs.

IV. CO-CONSPIRATORS

24. With respect to all of the conduct complained of below, at all relevant times Defendants GSK and Biovail acted in concert.

25. Various other persons, firms and corporations not named as Defendants herein have participated as co-conspirators with Defendants in the violations alleged herein and have performed acts and made statements in furtherance thereof.

V. LEGAL BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs and Substitution of Generics for Brand name Drugs

26. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§301-392 ("FDCA"), a manufacturer of a new drug must obtain approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data

concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

27. In 1984, Congress amended the FDCA by enacting the Hatch-Waxman amendments, called the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman"). The purpose of Hatch-Waxman was to hasten the delivery of inexpensive generic drugs to the market while respecting the patent rights of brand name drug patent holders.

28. Hatch-Waxman represents a significant effort by Congress to hasten the delivery of generic drugs to the market. The principal mechanism Congress used was to eliminate the need for generic manufacturers to file a lengthy and costly NDA to obtain FDA approval for generic substitutes. Instead, under Hatch-Waxman, to obtain approval, the generic manufacturer is permitted to file an ANDA that incorporates the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA and then show only that the proposed generic drug is bioequivalent to the brand name drug, *i.e.*, that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug.

29. Once bioequivalence is demonstrated, the FDA assigns an "AB" rating to the generic drug, permitting it not only to be sold, but also to be substituted (and in some instances, *required* to be substituted), for the brand name drug at the pharmacy counter.

30. To protect brand name manufacturers' ability to enforce their patents against infringement through the ANDA process, Hatch-Waxman also streamlined the patent enforcement process, providing that the FDA could not grant a generic manufacturer final

approval to market or sell a generic version of the brand name drug for up to 30 months if the patent holder initiated a patent infringement lawsuit against the ANDA applicant.

31. When the FDA approves a brand name manufacturer's NDA, Hatch-Waxman allows the brand manufacturer to list in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") any patents that the brand manufacturer believes could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand name drug prior to the expiration of the listed patents.

32. The FDA plays only a ministerial role in Orange Book listings. The FDA relies completely on the brand name manufacturer for information concerning the validity of the patents and applicability of the patents to the brand name drug. The FDA does not check the representations supplied by the brand name manufacturer independently for accuracy or trustworthiness.

33. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a brand name drug), a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

(a) that no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");

(b) that the patent for the brand name drug has expired (a "Paragraph II certification");

(c) that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

(d) that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

34. If a generic manufacturer files Paragraph I or II certifications, the FDA must act on the application within 180 days of receipt. If a generic manufacturer files a Paragraph III certification, the FDA can proceed with the ANDA approval process, with final approval being granted after the expiration of the applicable patents.

35. If a generic manufacturer files a Paragraph IV certification, however, a brand name manufacturer may delay the final FDA approval of the ANDA by suing for patent infringement. Specifically, if the brand name manufacturer initiates a patent infringement action against the generic filer within 45 days of the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of: (a) 30 months, or (b) issuance of a court decision that the patent is invalid or not infringed by the generic manufacturer's ANDA. During the pendency of the 30-month stay, the FDA may grant "tentative approval" to an ANDA applicant if the FDA determines that the ANDA would qualify for final approval but for the 30-month stay, but cannot authorize the generic manufacturer to go to market. Thus, by listing a patent in the Orange Book and filing a suit within 45 days of receiving a Paragraph IV certification regarding the listed patent, a brand name drug manufacturer may delay the date of final approval of the generic drug, and the generic drug's entry into the market.

36. Hatch-Waxman relies on the brand name manufacturer to refrain, both from listing patents that were improperly procured, or invalid, or not applicable to the brand name drug, and from bringing suit without proof that the generic applicant actually infringes a valid, enforceable, and applicable patent held by the brand name manufacturer.

37. Typically, generic versions of brand name drugs are priced significantly below their brand name counterparts. Because of the price difference and other institutional features of the pharmaceutical market, in every state, pharmacists are permitted (and in some states, required) to automatically substitute the generic product for a brand name product unless a doctor specifically requires a brand name product to be dispensed.

38. As additional generic manufacturers enter the market, prices for generic versions of a drug decrease predictably because of competition among generic manufacturers, and the loss of sales volume by the brand name drug to the corresponding generic accelerates. Generic competition enables purchasers to purchase generic versions of the brand name drug at a substantially lower price than the brand name drug.

39. Until a generic manufacturer enters the market, there is no bioequivalent generic drug that can substitute for the brand name drug, and therefore the brand name manufacturer can charge supra-competitive prices profitably without material loss to sales volume. As a result, brand name drug manufacturers have an obvious economic motivation to delay the introduction of generic competition into the market.

40. Thus, brand name manufacturers' abuse of Hatch-Waxman patent protections – through improper patent listing or the commencement of baseless litigation – improperly prevents generic competitors from bringing less expensive bioequivalent substitute products to market, violates antitrust law, and harms purchasers of pharmaceutical products.

B. The Availability of Citizen Petitions to Challenge FDA Approval of Generic Drugs

41. Section 505(j) of the FDCA creates a mechanism by which a person may file a petition with the FDA requesting, among other things, that the agency take (or refrain from taking) any form of administrative action. This mechanism is commonly referred to as a "citizen petition".

42. Citizen petitions provide an opportunity for individuals to express genuine concerns about safety, scientific, or legal issues regarding a product anytime before, or after, its market entry.

43. The FDA regulations concerning citizen petitions require the FDA Commissioner to respond to each citizen petition within 180 days of receipt. That response may be to approve the request in whole or in part, or deny the request. The Commissioner also may provide a tentative response with an estimate on a time for a full response.

The regulations dictate the form of a citizen petition, but place no restrictions on their subject matter.

44. Reviewing and responding to citizen petitions is resource-intensive and time-consuming because the FDA must research the petition's subject, examine scientific, medical, legal and sometimes economic issues, and coordinate internal agency review and clearance of the petition response. These activities strain the FDA's limited resources.

45. In July 2006, Gary Buehler, R.Ph. ("Buehler"), Director of the Office of Generic Drugs Center for Drug Evaluation and Research ("CDER") at the FDA, noted that of 42 citizen petitions raising issues about the approvability of generic products, "very few… have presented data or analysis that significantly altered FDA's policies." Of these 42, only three petitions led to a change in FDA policy on the basis of data or information submitted in the petition.

46. Until September 2007, it was well known in the pharmaceutical industry that the FDA's practice was to withhold ANDA approval until after it had responded to any applicable citizen petitions. On this subject, Buehler acknowledged that "[i]t is very rare that petitions present new issues that CDER has not fully considered, but the Agency must nevertheless assure itself of that fact by reviewing the citizen petitions."

47. In recent years, a number of brand name pharmaceutical manufacturers abused the citizen petition process, using it as a tactic to extend their monopolies on name brand drugs.[1] Indeed, citizen petitions by rival companies rarely raise legitimate concerns about the safety or efficacy of generic products, usually seeking only to preserve an existing monopoly past a statutorily-granted period of exclusivity. Drug companies frequently file citizen petitions on the eve of FDA approval of an ANDA for competing AB-rated generic drugs, even though the petitioner could have made the same arguments months, or even years, before. This delays the final approval of a pending ANDA filing for at least several months while the FDA evaluates the citizen petition.

48. The FDA acknowledges citizen petition abuse: it has "seen several examples of citizen petitions that appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application but rather to try to delay the approval simply by compelling the agency to take the time to consider arguments raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before."

49. The abuse of the citizen petition process helped lead Congress to enact the FDA Amendments Act of 2007, 21 U.S.C. 355(q) (the "2007 Amendments"). In pertinent part, the

[1] *See* Comment of the Staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission, at http://www.ftc.gov/be/v000005.pdf, at p. 1, *et seq.*

2007 Amendments provide that the FDA shall not delay approval of a pending ANDA because of a citizen petition unless the FDA determines that a delay is necessary to protect the public health. The 2007 Amendments also authorize the FDA to summarily deny any citizen petition whose primary purpose, as determined by the FDA, is to delay competition. Signed into law on September 27, 2007, these revisions were not yet in effect at the time the FDA was considering the petitions at issue here.

VI. FACTUAL BACKGROUND

A. The Formulation of Bupropion Hydrochloride, or Wellbutrin IR

50. Bupropion hydrochloride affects chemicals in the brain (neurotransmitters) that nerves use to transmit messages. When nerves transmit messages, they recycle released neurotransmitters in a process referred to as reuptake. Bupropion hydrochloride works by inhibiting the reuptake of such neurotransmitters as dopamine, serotonin, and norepinephrine. This action makes more dopamine, serotonin, and norepinephrine available to transmit messages to other nerves, mitigating a neurotransmitter imbalance that some experts believe causes depression.

51. In 1966, Burroughs Research first synthesized bupropion hydrochloride. In 1974, Burroughs-Wellcome, a predecessor to GSK, obtained the original patent for bupropion. In the 1980s, the first form of bupropion hydrochloride was formulated for domestic use in the United States. In 1985, the FDA approved this formulation for marketing.

52. Bupropion hydrochloride was first marketed by Burroughs-Wellcome under the brand name Wellbutrin. In usage, bupropion hydrochloride was sold in the form of a tablet that released more than 75% of its bupropion hydrochloride into the dissolution media in 45 minutes. As such, it was an "instant release" formulation.

53. Bupropion hydrochloride may be differentiated from other antidepressants in that its major effect is on dopamine, an effect not shared by selective serotonin reuptake inhibitors like paroxetine (Paxil), fluoxetine (Prozac), and sertraline (Zoloft), or by tricyclic antidepressants like amitriptyline (Elavil), imipramine (Tofranil), and desipramine (Norpramin). Because bupropion hydrochloride can be chemically differentiated from other antidepressants -- and because these differences gave rise to beliefs in differing side effect profiles -- Wellbutrin enjoyed monopoly-priced, brand name sales during the late 1980s and early 1990s.

B. The Development of Sustained Release Bupropion, or Wellbutrin SR

54. By the early 1980s, Burroughs-Wellcome believed that the instant release tablet might be associated with a side effect of seizures in some users, and that a controlled, sustained release of bupropion hydrochloride might reduce the rate of seizure. Burroughs-Wellcome and its contractors researched pharmaceutical delivery systems in order to accomplish controlled sustained delivery of bupropion hydrochloride. In doing so, Burroughs-Wellcome worked in an already crowded area of intellectual property for sustained release approaches to similar active ingredients for pharmaceutical products.

55. The rate of drug release from solid dosage forms may be modified by numerous technologies, which in general are based on: (a) modifying drug dissolution by controlling access of biologic fluids to the drug through use of barrier coatings; (b) controlling drug diffusion rates from dosage forms; and (c) chemical reaction or interaction between drug substance or its pharmaceutical barrier to site-specific biologic fluids. Among the available methodologies are: (a) coated beads, granules, and microspheres; (b) micro-encapsulated drugs; (c) sustained-release, extended-release, time-release, controlled-release, or continuous-release tablets or capsules; and (d) embedding the drugs in slowly eroding or hydrophilic matrix systems.

56. Burroughs-Wellcome opted to have its contractors create a novel, "osmotic pump" pharmaceutical delivery system which could be used for a variety of active ingredients, including bupropion hydrochloride. Although other, more conventional methods by which to achieve the controlled, sustained release of active ingredients such as bupropion hydrochloride were known publicly, by developing a novel "osmotic pump" system, Burroughs-Wellcome hoped that its launch of sustained release products (including a version of Wellbutrin) would enjoy patent protection over and above the existing patent protection it had for the currently-marketed products (including Wellbutrin instant release).

57. By the late 1980s, Burroughs-Wellcome realized that its patented "novel" approach for an osmotic pump system was not so novel. Burroughs-Wellcome commenced re-issuance proceedings that would result in the withdrawal of the patent protection previously obtained for the "osmotic pump" system, with the hope of preserving some protection of longer release Wellbutrin.

58. Burroughs-Wellcome later pursued a matrix formulation method for accomplishing a controlled, sustained release of bupropion hydrochloride. Using one of many known, off-the-shelf water-soluble cellulose derivatives, hydroxypropol methylcellulose ("HPMC"), Burroughs-Wellcome formulated a controlled, sustained release bupropion hydrochloride product for twice-a-day usage.

59. Because the use of water-soluble cellulose derivatives for sustained release pharmaceutical products was common knowledge long before this time, Burroughs-Wellcome had to narrowly tailor its patent application to a matrix tablet for bupropion hydrochloride using the specific water-soluble cellulose derivative employed in its product, i.e., hydroxypropol methylcellulose. Only through this limitation -- and by requiring the combination of specific

ingredients with the bupropion hydrochloride to accomplish specific dissolution rates -- could Burroughs-Wellcome muster an arguably patentable invention.

60. By 1996, the FDA granted final approval to the NDA for a controlled, sustained release bupropion hydrochloride to be marketed as Wellbutrin SR. The matrix formulation for Wellbutrin accomplished a twice-in-a-day dissolution rate for bupropion hydrochloride.

61. From the 1996 launch of Wellbutrin SR, and for years afterwards, GSK and its predecessors enjoyed significant revenues from the sale of Wellbutrin SR, the twice-a-day formulation of bupropion hydrochloride.

62. Because the patent for the formulation was expressly limited to the use of only one off-the-shelf excipient HPMC, companies seeking to market generic formulations of Wellbutrin SR accomplishing similar bioavailability, but using other excipient techniques, found success.

63. In turn, GSK sought to stave off the entry of generic Wellbutrin SR by filing patent infringement litigation to prolong its Wellbutrin SR monopoly position, even though it knew that its claims would ultimately be proven meritless.

64. At the same time, GSK looked for other opportunities to continue to prolong its monopoly position of bupropion hydrochloride products, and it sought to gain that position before generic entry of Wellbutrin SR occurred in order to leverage the Wellbutrin SR position. GSK eventually turned to Biovail for yet another line extension for bupropion.

C. The Development of Extended Release Bupropion, or Wellbutrin XL

65. In the 1990s, Biovail began to collaborate with a sophisticated pharmaceutical technology company, Pharma Pass, LLC ("Pharma Pass"), to develop different formulations of controlled release bupropion hydrochloride. Located in Irvine, CA, Pharma Pass had expertise as a developer of advanced oral controlled release technologies and formulations that have been

licensed to pharmaceutical companies in the United States and Europe. Pharma Pass was headed by its principal owner, Dr. Pawan Seth, who was a prolific developer of controlled release technologies.

66. In seeking to formulate a once-a-day extended release bupropion hydrochloride product, Pharma Pass was working in the highly crowded area of extended release approaches for pharmaceutical products. Pharma Pass knew that it had chosen a path that had been travelled many times before – the use of a core containing conventional excipients along with a coating for sustained / controlled / delayed release formulations. Pharma Pass chose a core comprising bupropion hydrochloride surrounded by conventional excipients, aware that this mechanism was nothing remarkable or worthy of patent protection in and of itself. Pharma Pass based its coating on an off-the-shelf chemical called ethylcellulose (Ethocel) that, itself, was nothing remarkable or innovative: Ethocel was marketed and sold by Dow Chemical as a coating for drug products that would protect and perform sustained-release functions. Pharma Pass' coating used two other ingredients: a plasticizer and a water-soluble polymer. Pharma Pass knew that these three ingredients had previously been used to perform extended-release functions in other pharmaceutical products, and was nothing remarkable or worthy of patent protection in and of itself.

67. When Pharma Pass set out to formulate its once-a-day approach for bupropion hydrochloride, information available in the public domain already taught the essential features as to how to formulate controlled / sustained / extended release formulations of chemicals such as bupropion hydrochloride using a core comprising the active ingredient and conventional excipients, and a coating consisting essentially of a water-insoluble, water-permeable film-forming polymer, a plasticizer, and a water-soluble polymer.

68. In undertaking laboratory tests to identify the ratios for its ingredients, Pharma Pass reached the predictable conclusions that would occur from the admixture of these off-the-shelf types of ingredients. For example, because Pharma Pass was not including in the admixture a stabilizer such as an acidic compound, it knew that the properties of the well-recognized coating might provide adequate absence of degradation of bupropion hydrochloride even though no stabilizer was present in the formulation. Further, because the properties of the coating were known to, and indeed marketed as, accomplishing controlled/sustained/extended release functions, it was predictable that the coating of the product would achieve extended release functions even though no other, additional approach to extended-release was being used (e.g., an "osmotic pump" approach).

69. In 1998, Pharma Pass began to seek patent protection for a once-a-day formulation for bupropion hydrochloride, i.e., for its coated core formulation using off-the-shelf ingredients marketed for the purpose of creating protective, extended-release coatings for pharmaceutical products. In doing so, Pharma Pass grappled with the reality that its purported invention was based upon materials and techniques long disclosed in the public domain and used for other pharmaceutical products. To obtain patent approval, Pharma Pass hung its hat on the argument that its claimed invention was "free of stabilizer of any kind": "the invention thus provides a new bupropion hydrochloride controlled-release composition under the form of a tablet free of stabilizer of any kind...." *See* Pharma Pass '341 Patent Documents (attached as Exhibit A).

70. Pharma Pass sought to patent this claimed new invention by filing an application with the United States Patent and Trademark Office, which later resulted in the issuance of U.S. Patent No. 6,096,341 (the "'341 patent").

D. The Application Leading to the '341 Patent

71. A review of Pharma Pass' application for extended release bupropion hydrochloride shows that Pharma Pass, and later Biovail, intentionally described the invention and its claims for patent protection to be "free of stabilizer" in the ordinary sense of that expression: the tablet is free of any substance or agent that tends to prevent changes in the chemical integrity of a tablet. *See* Exhibit A. No less than nine separate reasons support the conclusion that the subject of Pharma Pass' submission was free of any stabilizer.

72. First, Pharma Pass was familiar with the importance of claim construction in approval of the patent and protection from infringement, and was specifically well aware of the requirements under 35 U.S.C. §112.[2] Pharma Pass carefully constructed the '341 patent to highlight this claimed invention by concentrating on a claimed achievement of a bupropion hydrochloride formulation that is "free of stabilizer." *See* Exhibit A at 1-4. Indeed, both Claim 1 and Claim 30 of the '341 patent expressly described the patented formulation both as "*free of stabilizer*" and as "*free of stabilizer of any kind*" (emphasis added).

73. Second, the Manual of Patent Examining Procedure ("MPEP") relied upon by the United States Patent and Trademark Office when approving patents and by patentees like Pharma Pass when constructing patents, advises that "the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification." Pharma Pass

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[2] 35 U.S.C. §112 provides:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.
>
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

definitively chose to use the language "free of" in its '341 patent, knowing that this term would be assigned its plain, ordinary and customary meaning since it is not a term having special meaning in the pharmaceutical context.

74. Third, Pharma Pass, like all patentees, "is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning(s)." Pharma Pass chose not to act as its own lexicographer and define "free of" in a different manner from its ordinary meaning in the '341 patent. The word "stabilizer" is a concept well understood in the pharmaceutical art as something that provides stability. Aware that chemical dictionaries define "stabilizer" as "[a]ny substance that tends to keep a compound, mixture, or solution from changing its form or chemical nature," Pharma Pass again did not act as its own lexicographer and define "stabilizer" differently from the meaning of the term that would be applied by one of ordinary skill in the art. *See* Hawley's Condensed Chemical Dictionary 1042 (13th ed. 1997).

75. Fourth, Pharma Pass used the term "free of stabilizer" as a negative limitation to define the claimed invention by what it was not. Negative limitations of this sort are commonly used by patentees in order to exclude the characteristics of prior art. *See* MPEP. Pharma Pass was well aware that, pursuant to 35 U.S.C. §§102 and 103, its patent could be rejected based upon prior art. As recognized in the section of the '341 patent entitled, "Background of the Invention," Pharma Pass highlighted that the use of stabilizers was critical in the prior art:

> U.S. Pat. No. 5,358,970 and U.S. Pat. No. 5,427,798 both to Burroughs Wellcome [predecessor to Defendant GSK], describe a sustained release formulation of bupropion hydrochloride based on a matrix technology… *As bupropion hydrochloride is unstable, the product described in the above patents requires a stabilizer to*

> *achieve stability*. This stabilizer is an acidic compound, preferably cysteine hydrochloride.

See Exhibit A at 3 (emphasis added).

76. Fifth, the complete absence of stabilizer in Defendants' bupropion hydrochloride extended release formulation, including stabilizers composed of acid, was a cornerstone of the invention and is necessary to distinguish it from the prior art. As reflected in the '341 patent section entitled "Summary of the Invention," which is used to inform the public of the claimed invention:

> *The invention thus provides a new bupropion hydrochloride controlled release composition under the form of a tablet free of stabilizer of any kind including those with acidic pH or antioxidant properties.*

See Exhibit A at 3 (emphasis added).

77. To further underscore the importance of the negative limitation of the absence of stabilizer in the bupropion hydrochloride extended release and the novelty of the invention, the '341 patent section entitled, "Detailed Description of the Invention," further explains:

> *Surprisingly, it was discovered that the formulation did not lead to any degradation of bupropion hydrochloride though no stabilizer* was present in the formulation. Stability studies were conducted in oven, under the storage test conditions described in the US pharmacopoeia 23rd edition page 1961. Under these conditions no significant change in drug potency could be seen.

See Exhibit A at 4 (emphasis added). Thus, the absence of stabilizer in the bupropion hydrochloride extended release formulation to be marketed as Wellbutrin XL was the critical distinguishing characteristic of the '341 patent from the prior art and the validity of the patent hinged on the free of stabilizer claim.

78. Sixth, Pharma Pass' use of the tool of negative claim limitations assured that "free of stabilizer" would mean the absence of any stabilizer. According to the MPEP at §2173.05(i),

a claim may contain a limitation that explicitly excludes subject matter that would otherwise fall within its boundaries. Such limitations are acceptable (not indefinite) so long as the boundaries of the claim are clear. In Pharma Pass' application, the claim 1 the recitation of the core element uses open claim language ("comprises", a patent term of art meaning including but not limited to) to indicate that the core can contain the elements recited and additional unspecified elements, which could include stabilizers. To avoid the prior art on stabilizers, Pharma Pass' application specifically disclaimed the use of stabilizer in the claim by saying "free of stabilizer". The negative limitation renders the claim element inclusive of the recited elements and unspecified elements, but excludes the use of stabilizer. And the boundary was clear, as it excluded stabilizer of any kind.

79. Seventh, if the patentee manifests an intent to exclude or limit the claim terms, disclaimers made over the prior art in the specification or specific definitions used by the patentee will limit the scope of the claim element. In the case of Pharma Pass' application for the extended release bupropion, the specification is replete with references that distinguish the invention over the prior art based on stabilizer. In its '341 application, Pharma Pass described the prior art as needing a stabilizer, "an acidic compound, preferably cysteine hydrochloride", sufficient to achieve stability. *See* Exhibit A at 3. The summary of the invention describes the invention as being "free of stabilizer of any kind including those with acidic pH or with antioxidant properties." *Id.* at 3. The formulation was successful, despite that "no stabilizer was present in the formulation." *Id.* at 4. Moreover, none of the examples of the invention used by Pharma Pass use a stabilizer of any kind or in any amount. *Id.* at 4-6.

80. Eighth, that Pharma Pass intended its stabilizer amount to be zero is further supported by traditional claim drafting principles. Generally, in order to not be restricted to a

specific numerical parameter, claims are drafted using imprecise words like "approximate," "substantially," or "about" to capture potential infringers. If Pharma Pass wanted to capture the range of stabilizer from zero up to the lowest amounts in the prior art, it could have written the claims to either define "no" or "free" to mean some amount from zero to X, or drafted the claim language such that "free" was qualified using the accepted terms: e.g. "substantially free of stabilizer" or "substantially no stabilizer" again with some mathematical or definitional quantification. Given that the specification is replete with references to "no stabilizer" and "free of stabilizer", the examples show no stabilizer, and the lack of qualifying language with the terms of "free" and "no", show that Pharma Pass drafted the application intending to limit the term "free" of stabilizer to its usual and customary meaning of none or zero. *See generally* Exhibit A.

81. Ninth, the definition of stabilizer is broader than the stabilizer term used in the cited prior art. The summary of the invention describes the invention as being "Free of stabilizer of any kind including those with acidic pH or with antioxidant properties." *See* Exhibit A at 3. Thus, free of stabilizer means free of any stabilizer, including the smaller subset of materials with acidic pH and antioxidant properties (such as cysteine HCl).

82. Thus, by its use of the negative limitation in the claim "free of stabilizer" and its unqualified use of the word "free" in the claims and specification, Pharma Pass plainly intended to claim, and did claim, compositions that had a zero amount of stabilizer in the formulation, in accordance with the usual and customary definition of the word "free".

E. Issuance of the '341 Patent

83. In August of 2000, and because Pharma Pass claimed to discover a bupropion hydrochloride formulation that was free of stabilizer and had constructed a patent to reflect this, the United States Patent and Trademark Office approved two formulation patents purporting to

cover Wellbutrin XL, the '341 patent, and U.S. Patent No. 6,143,327 ("the '327 patent"), a continuation of the '341 patent, issued on November 7, 2000. *See* Pharma Pass '327 Patent Documents (attached as Exhibit B). These patents were set to expire in 2018.

84. In December 2002, Biovail acquired Pharma Pass, and later formally obtained the rights conferred by the '341 and '327 patents for Wellbutrin XL.

85. Biovail, also a sophisticated pharmaceutical company, was familiar with the new formulation on which it collaborated with Pharma Pass and knowledgeable regarding patent construction and the primary distinguishing characteristic of the '341, was the creation of bupropion hydrochloride formulation which is "free of stabilizer."

F. Defendants Acted in Concert with Respect to the Development, Approval, Manufacture, Promotion, and Distribution of Wellbutrin XL

86. On October 26, 2001, Defendants Biovail and GSK entered into an agreement to develop, approve, manufacture, promote, and distribute the extended release formulation of bupropion, to be marketed as Wellbutrin XL.

The principal terms of the agreement between Biovail and GSK were as follows:

(a) GSK and Biovail would collaborate in the scientific development and regulatory approval of Wellbutrin XL;

(b) GSK would assist Biovail in qualifying a Biovail facility for manufacture of Wellbutrin XL, and Biovail was responsible for product manufacture;

(c) GSK and Biovail would co-promote Wellbutrin XL in the U.S. until GSK obtained approval from the FDA, Biovail retained the right to promote Wellbutrin XL in Canada; and

(d) GSK would pay royalties to Biovail for its development and manufacturing costs based on U.S. sales of Wellbutrin XL, and Biovail

would pay royalties to GSK based on Biovail's promotion and sale of Wellbutrin XL in Canada.

87. In August 2002, GSK filed an NDA seeking approval to market Wellbutrin XL. GSK listed the '341 and '327 patents in the Orange Book as covering Wellbutrin XL.

88. On August 28, 2003, NDA No. 21-515 covering formulations of Wellbutrin XL was issued to GSK and GSK began to market Wellbutrin XL. Pursuant to the agreement between the Defendants, Biovail served as the exclusive manufacturer of Wellbutrin XL.

89. Wellbutrin XL is an extended release formulation of bupropion hydrochloride. Extended release technology allows for the continuous and slow release of a drug into the patient's bloodstream over a period of time. Biovail and GSK have claimed that a principal advantage of the extended release form of extended release administration is that it increases patient compliance. Symptoms of depression include fatigue and loss of concentration – so that patients with depression may forget or neglect to take their prescribed medication. Biovail and GSK claim that, in the case of bupropion hydrochloride, better patient is compliance achieved with once-a-day extended release dosage.

90. Wellbutrin XL is sold in 150mg and 300mg tablets. The usual target dose is 300mg given once daily – initiated at 150mg/day and then increased to 300mg/day as early as day four, if adequately tolerated. The maximum total daily dose of Wellbutrin XL is 450mg.

91. On December 31, 2004, the '341 and '327 patents were formally assigned to Biovail. Biovail continues to be the exclusive manufacturer and supplier of Wellbutrin XL to GSK. In return, pursuant to the agreement between the Defendants, GSK pays Biovail royalties based on GSK's net sales of Wellbutrin XL.

92. By virtue of the co-promotion agreement between GSK and Biovail with respect to Wellbutrin XL, Defendants had a common interest in the development, approval, manufacture, promotion, and distribution of Wellbutrin XL.

93. According to a pharmaceutical industry study reported in the February 21, 2008 *Wall Street Journal*, GSK raised the price of Wellbutrin XL by 44.5% between 2005 and 2007.

94. Wellbutrin XL is identified in the pharmaceutical industry as a "blockbuster" drug. According to IMS data, for the 12 months ended September 2006, Wellbutrin XL 150mg tablets had U.S. sales of approximately $800 million, and the 300mg tablets had U.S. sales of approximately $972 million, yielding a total annual U.S. market for Wellbutrin XL of $1.8 billion. Wellbutrin XL is sold throughout the U.S., and was ranked in the pharmaceutical industry publication *Drug Topics'* Top 200 Brand Name Drugs by Dollars in 2006 at number 16.

G. ANDA Filings by Generic Competitors

95. In 2004 and 2005, four generic pharmaceutical product manufacturers sought to enter the bupropion hydrochloride extended release market with inexpensive AB-rated bioequivalent generic formulations in 150 mg and 300 mg dosages.

96. Unlike the '341 and '327 patents, the generic competitors' ANDAs expressly stated that the generic formulations contained stabilizer.

1. Anchen

97. On September 21, 2004, Anchen filed an ANDA seeking FDA approval to market generic bupropion HCl extended release in 150 mg and 300 mg formulations. Anchen's ANDA included a Paragraph IV certification that its products would not infringe the '341 or '327 patents.

98. Anchen's ANDA repeatedly identifies a known stabilizer, diluted hydrochloric acid, as an ingredient in the proposed generic formulation, and the ANDA specification describes

the final tablet granulation as containing 0.00 to 1.00% hydrochloric acid. Hydrochloric acid is well-known to act as a stabilizer, and Patent No. 6153,223 states that hydrochloric acid is well-established in the art as being an effective stabilizer of bupropion hydrochloride products. To avoid any misunderstanding, Anchen's ANDA expressly states that the function of hydrochloric acid is to serve as a "stabilizing agent."

99. Use of hydrochloric acid as a stabilizing agent is nothing new to the Defendants. GSK's predecessor bupropion hydrochloride formulations use an acidic compound as a stabilizer. According to a SmithKlineBeecham memo dated 1983, "[t]he use of hydrochloric acid as a stabilizer for Bupropion Hydrochloride is well documented, and it is used in the current Wellbutrin tablet formulation." The memo explains that the use of hydrochloric acid "dramatically improve[s] product stability."

100. In November 2004, pursuant to Hatch-Waxman, Anchen notified Defendants of its ANDA and Paragraph IV certification.

2. Abrika

101. On September 23, 2004, Abrika submitted ANDA 77-285 seeking FDA approval to market a generic 150 mg formulation of bupropion HCl extended release. On October 1, 2004, Abrika amended its ANDA to include a 300 mg generic product.

102. Similar to Anchen, Abrika's ANDA expressly stated, among other things, that the generic formulation contained stabilizer.

103. In November 2004, pursuant to Hatch-Waxman, Abrika notified Defendants of its ANDA and its Paragraph IV certification.

3. Impax

104. On November 30, 2004, Impax filed ANDA 77-415 seeking FDA approval to market hydrochloride extended release generic bupropion in 150 and 300 mg formulations.

105. The ANDA filed by Impax expressly stated that its generic formulation contained stabilizer.

106. On January 20, 2005, pursuant to Hatch-Waxman, Impax notified Defendants of its ANDA and its Paragraph IV certification.

4. Watson

107. On July 21, 2005, pursuant to Hatch-Waxman, Watson notified Defendants of its ANDA 77-715 seeking pre-patent expiration approval to market a generic version of Wellbutrin XL in a 300 mg formulation and its Paragraph IV certification.

108. The ANDA filed by Watson expressly stated that its generic formulation contained stabilizer.

H. Defendants Filed Sham Litigation To Delay Generic Entry

109. Beginning late 2004, Defendants individually, or in concert, commenced sham infringement actions against each of the four generic manufacturers after Defendants were notified of their ANDAs. The actions were filed by the Defendants for the improper purpose of preventing entry of the competing generic products into the market. These sham infringement actions were objectively baseless in that no reasonable litigant could realistically expect success on the merits. The ANDAs did not infringe on the '341 patent given that each of the generics' products contained stabilizer.

110. On December 21, 2004, Defendants GSK and Biovail filed an action in the United States District Court for the Central District of California against Anchen alleging infringement of the '341 and '327 patents.

111. That same day, Defendants GSK and Biovail filed an action in the United States District Court for the Southern District of Florida against Abrika alleging infringement of the '341 and '327 patents.

112. On March 7, 2005, Biovail filed an action in the United States District Court for the Eastern District of Pennsylvania against Impax alleging that ANDA 77-415 infringed the '341 patent.

I. The Generic Formulations Did Not Infringe the '341 Patent and the Actions Filed by Defendants Alleging Infringement Were A Sham

1. It was Clear from the Applications, Data, and Samples Available to Defendants that the Generic Substitutes Were Not Free of Stabilizer

113. Given that the validity of the '341 patent rested on Defendants' purported surprising discovery that the claimed formulation of bupropion HCl extended release was "free of stabilizer," Defendants were necessarily attuned to this claim in evaluating the non-infringement claims by generic competitors.

114. The generic competitors' ANDAs, however, expressly stated that the generic formulations contained stabilizer. Anchen's ANDA, for example, repeatedly identifies diluted hydrochloric acid as an ingredient in the proposed generic formulation, and the ANDA specification describes the final tablet granulation as containing 0.00 to 1.00% hydrochloric acid. Further, although hydrochloric acid is well-known to work as a stabilizer, to avoid any misunderstanding, the ANDA expressly states that the function of hydrochloric acid is to serve as a "stabilizing agent."

115. In addition, all of the generic competitors provided Defendants with access to their ANDAs and sample products to allow Defendants to determine for themselves that the generic formulations were not free of stabilizer.

116. For example, Defendants obtained access to Impax's ANDA 77-415, as well as additional data, before they filed suit, and GSK sought and received permission from its two outside experts to review Impax's ANDA formulation and related data. In addition, Defendants

received the alleged composition of the Impax formulation, along with samples of that product, on July 20, 2005, while their action was in its early stages.

117. Similarly, Abrika supported its assertions made in its Paragraph IV certification by offering Defendants access to relevant portions of its ANDA under the condition that, if the facts in Abrika's notice proved to be true, Defendants would not sue for infringement. Defendants refused this offer. Abrika provided its ANDA on May 26, 2005.

118. Defendants brought and maintained the patent infringement actions without analyzing the materials that would have shown them their claims were baseless. For example, neither the complaint nor the amended complaint filed against Impax described how the Impax product might infringe the '341 patent. Instead, the pleadings simply acknowledge that Biovail *reviewed* the Impax's ANDA and "believe[s] that it infringes" the '341 patent "based on information provided."

119. Further, despite having been ordered by the court in the *Impax* litigation to disclose the basis for their infringement claims by October 2005, as of February 2006, Biovail still had not done so.

120. Defendants brought and maintained infringement actions against the generic competitors despite knowing or having reason to know that the generic competitors' formulations of bupropion HCl extended release did not infringe because they were not free of stabilizer. The actions were therefore objectively baseless.

2. All Court Rulings on the Claims Rejected Defendants' Allegations that the Generic Products were Free of Stabilizer and Therefore Infringed

121. Not surprisingly, all of the courts that have reviewed Defendants' infringement claims have rejected Defendants' strained attempts to show that the competing generic products were free of stabilizer. *See Biovail Laboratories, Inc. v. Anchen Pharmaceuticals. Inc.,* Case No.

SACV 04-1468-JVS (RCx) (C.D. Cal. Feb. 8, 2006) (attached as Exhibit C); *Biovail Laboratories International SRL v. Impax Laboratories, Inc.*, 433 F. Supp. 2d 501 (E.D. Pa. May 23, 2006) (attached as Exhibit E); and *Biovail Laboratories International SRL v. Abrika, LLLP*, Case No. 04-61704-CIV (S. D. Fla. Aug. 23, 2006) (attached as Exhibit F). Further, in the only action in which a dispositive motion was decided, the Court granted summary judgment for the generic competitor, ruling that the proposed generic formulation *did not infringe* the '341 patent because it contained stabilizer. *See Biovail Labs., Inc. v. Anchen Pharmaceuticals., Inc.*, Case No. SACV 04-1468-JVS (RCx) (C. D. Cal. Aug. 1, 2006) (attached as Exhibit D).

122. The *Anchen* court was first to rule. At the *Markman* hearing, Biovail took a completely different position on the meaning of the terms "free of" and "stabilizer" than the position Pharma Pass took in its '341 patent application. To obtain the patent, Pharma Pass drafted its application so that "free of stabilizer" or "free of stabilizer of any kind" would mean that the tablet would be free of any substance or agent tending to prevent changes in the chemical integrity of the tablet. After generic companies filed their ANDAs and Defendants initiated their frivolous litigation, Biovail took the opposite position, arguing that "free of" and "stabilizer" should have specialized interpretations.

123. Predictably, the *Anchen* court ruled that "reliance on Webster's dictionary is proper in this case" and that Defendants' "proposed definition of 'stabilizer' is not found anywhere in the '341 patent, and actually contradicts the summary of the invention." *See* Exhibit C at 8-9.

124. Following the *Markman* hearing, the *Anchen* court, ruling on summary judgment, "found that based on the original ANDA, Anchen's ANDA is *not* free of stabilizer." As a result, the Court granted summary judgment on infringement in favor of Anchen. *See* Exhibit D at 20.

125. The *Impax* court ruled just as decisively. Once again, Biovail adopted a litigation position that was materially different than its patent application position. To obtain the patent, Biovail's predecessor Pharma Pass described an invention that was "free of stabilizer of any kind" in order to have a patentable invention. In the *Impax* litigation, in contrast, Biovail argued that to infringe the '341 patent a product still might have some stabilizer in it (and thus not be "free of stabilizer"). The court dismissed Biovail's complaints that the amount of stabilizer in the generic product was so small as to "not really be acting as a 'stabilizer,'" noting dryly that "[w]hile this argument may be of philosophical interest, it does not comport with the ordinary and accustomed meaning of 'free of stabilizer.'" *See* Exhibit E at 13. The Court further noted: "If the tablet did in fact contain a compound used for stabilizing the tablet, but simply not enough of it, one would not call it "free of stabilizer," but rather "lacking sufficient stabilizer." *Id.*

126. The *Abrika* court similarly rejected Biovail's arguments. The court considered the ordinary meaning of the patent language, and concluded that the Defendants' "narrow construction contradicts the express disclosure of the patent that the claimed invention is 'free of stabilizer of any kind.'" *See* Exhibit F at 28. The court's analysis was animated by the distinction between the prior art, which contained stabilizers, and novelty of the purported invention reflected in the '341 patent, which does not. *Id. at* 27-29.

J. GSK Participated in the Sham Litigation

127. The sham infringement actions brought against *Anchen* and *Abrika* were filed by both GSK and Biovail. *See generally* Exhibits C, D, and F. In addition, in the *Watson* action, GSK was a party to the action as a counterclaim defendant. *See generally* Exhibits C-H. In the course of these actions, the generic manufacturers learned that the co-promotion agreement between the Defendants did not extend ownership rights under the '341 or '327 to GSK such that

GSK would have standing to sue for patent infringement. In response to Abrika's motion to dismiss GSK, GSK stated that it should be permitted to remain in the action because "[a]n injunction is as important to SmithKline as it is to Biovail."

128. Subsequently, GSK moved to withdraw as a plaintiff from the *Abrika* action. In seeking leave to withdraw, GSK represented to the Court that it would be "bound by the decision in the [*Abrika*] action," not sue with respect to the patents and the ANDA products at issue in the action, and provide discovery "as if it were a party to this action." GSK also subsequently withdrew from the *Anchen* action.

129. GSK was not a party to the *Impax* infringement action, but is identified in the complaint filed by Biovail as the owner of the NDA for Wellbutrin XL, the exclusive licensee of the '341 patent, the party responsible for the listing of the '341 patent in the Orange Book, and the seller of Wellbutrin XL.

130. GSK made clear by its filing and withdrawal in the *Anchen* and *Abrika* actions that it remained a real party in interest in the infringement actions, would continue to act in concert with respect to matters involving Wellbutrin the XL sham litigation and petitioning activities, and would continue to benefit from the anticompetitive conduct alleged herein.

131. GSK's continued interest and involvement in the infringement litigation is underscored by the action took at the close of the *Abrika* litigation. Particularly, at the time Biovail settled the action, GSK filed a motion seeking leave to review all sealed documents within the docket in order to protect all GSK documents from public disclosure. Subsequently GSK requested that all such documents be destroyed. GSK's request shows that its involvement and interest in the infringement litigation extended beyond the date of its withdrawal from the litigation.

K. Listing The '327 Patent In The Orange Book Was A Sham

132. The '327 patent is a continuation of the '341 patent. Like the '341 patent, the '327 patent provides for a bupropion HCl extended release tablet, free of stabilizer. Unlike the '341 patent, the '327 patent also provides a second coat consisting of a polymer and a plasticizer which assists in controlling the release.

133. The formulation as described in the '327 patent, however, does not conform to the FDA's requirements for bioequivalence with the parent drug. Particularly, the pharmacokinetic and relative bioavailability data show that the formulation as taught in the '327 patent does not display a bioavailability profile within 80%-125% of the bioavailability profiles of the bupropion HCl parent formulations, as is required by FDA bioequivalence regulations.

134. Accordingly, the '327 patent could not reasonably be asserted against a generic manufacturer of Wellbutrin XL and, therefore, should not have been listed in the Orange Book as covering Wellbutrin XL.

135. GSK and Biovail knew, or had reason to know, that the '327 patent did not cover Wellbutrin XL. Despite that, Defendants caused the '327 patent to be listed in the Orange Book referenced to Wellbutrin XL.

136. Despite their knowing improper listing of the '327 patent in the Orange Book, in lodging their infringement actions against Anchen and Abrika, GSK and Biovail asserted infringement not only of the '341 patent, but also the '327 patent. No reasonable litigant could realistically have expected success on the merits of an infringement action based on the '327 patent because the patent did not cover Wellbutrin XL. Rather, the claim was solely asserted to delay generic competition and maximize Defendants' Wellbutrin XL profits.

137. After filing their lawsuits against Anchen and Abrika, Defendants commenced actions against Impax and Watson, raising claims only under the '341 patent. In addition,

Defendants also subsequently voluntarily withdrew their claims under the '327 patent. Defendants took these actions because they knew they had improperly listed the '327 patent in the Orange Book and commenced litigation based on it, and knew they had been exposed.

138. On September 6, 2005, Biovail filed an action in the United States District Court for the Southern District of New York against Watson alleging that Watson's ANDA infringed the '341 patent.

139. On November 14, 2005, the FDA granted tentative approval to Anchen's ANDA for 150mg and 300mg bupropion hydrochloride extended release on November 14, 2005. Anchen was the first generic manufacturer to file an ANDA for 150mg and 300mg bupropion hydrochloride extended release, and as such, was entitled to 180 days of market exclusivity. Because of the Defendants' sham litigation, Anchen was unable to manufacture and market its generic version of Wellbutrin XL despite the FDA's tentative approval. *But for Defendants' baseless infringement lawsuit, generic bupropion hydrochloride extended release would have been available on the market on November 14, 2005.*

L. Defendants' Sham Citizen Petition Was Filed To Delay Generic Entry

140. On December 20, 2005, more than a year after the generic manufacturers filed their ANDAs, and a month after the FDA determined that Anchen's generic bupropion HCl extended release formulation was bioequivalent to Wellbutrin XL and gave tentative approval to Anchen's ANDA, Biovail filed a citizen petition with the FDA. *See* Biovail's December 20, 2005 citizen petition (attached as Exhibit G). Biovail's citizen petition was not based on any information or data that was not previously available to Defendants.

141. The citizen petition asked the FDA to refuse any bupropion HCl extended release ANDA that did not incorporate additional studies and data concerning bioequivalence including, in particular, data demonstrating not only that the generic bupropion HCl extended release

formulations were bioequivalent to Wellbutrin XL, but also that they were bioequivalent to the parent drugs, Wellbutrin IR and Wellbutrin SR.

142. Under Hatch-Waxman and FDA regulations, an ANDA product need be shown to be bioequivalent only to the referenced listed drug upon which the requested ANDA approval is predicated. In fact, Hatch-Waxman specifically forbids the FDA from requiring an ANDA to contain bioequivalence information from other than the referenced listed drug.

143. Many branded extended release drugs that were approved as part of a line extension from immediate release versions of the drug were approved based on bioequivalence studies as between the branded extended release and branded immediate release products. The FDA has never deemed it necessary or appropriate to require ANDA applicants to conduct their own bioequivalence studies comparing a generic extended release drug to the branded immediate release product.

144. Before approving brand-name Wellbutrin XL, the FDA required GSK to prove that Wellbutrin XL was bioequivalent to Wellbutrin IR and Wellbutrin SR. In addition, prior to approving the bupropion HCl extended release ANDAs, the FDA required the generic manufacturers to prove that their products were bioequivalent to Wellbutrin XL.

145. Thus, the demands for additional bioequivalence studies and data set forth in the citizen petition were contrary to both Hatch-Waxman's mechanisms to avoid time-consuming and redundant studies, and FDA protocols -- and were therefore without basis in law or practice. Moreover, the studies supporting the generic manufacturers' ANDAs were sufficient to demonstrate the bioequivalence Biovail purported to demand. Thus, there was no rational, scientific, or legal basis to require bioequivalence studies between generic bupropion HCl extended release applicants and the Wellbutrin parent drugs.

146. Biovail's citizen petition also demanded additional studies to measure three metabolites in the ANDA applicants' products. Biovail, however, offered no competent support for imposing this broad additional bioequivalence requirement. Moreover, the FDA's industry guidance publication makes clear that such additional requirements are generally unnecessary. Thus, the demand for metabolite studies was overbroad and fundamentally baseless.

147. The citizen petition was objectively baseless, in that it relied on unsubstantiated theories, lacked scientific support, misapplied governing legal and regulatory standards, and was nothing more than a last-minute attempt to extend Defendants' monopoly on an overpriced brand name drug by slowing market entry of bioequivalent and more affordable generic products through the abuse of governmental processes. In short, it was a sham.

148. On December 14, 2006, the FDA denied Biovail's citizen petition and condemned Biovail's conduct, stating that it did not have "the right to be free of generic competition" once its patents had been held to be unenforceable, and that under these circumstances, "Biovail [should] not be permitted to shield its market share." *See* December 14, 2006 FDA decision on Biovail's citizen petition (attached as Exhibit H). The FDA ruled that the generic manufacturers' bupropion HCl extended release products and Wellbutrin XL "would be expected to have the same clinical effect and safety profile when administered under the conditions for use prescribed, recommended, or suggested in the labeling. Y*ou have not submitted any data or information to suggest otherwise.*" *Id.* at 7 (emphasis added).

149. In addition, notwithstanding its acquiescence to Biovail's request for measurements of the hydroxybupropion metabolite, the FDA disparaged the Biovail submission, noting: "*You did not submit any evidence* in the Petition to support the conclusion that [the other metabolites] contribute meaningfully to safety and/or efficacy of Wellbutrin XL." *Id.* at 10, n.

32 (emphasis added). The FDA similarly criticized Biovail for failing to submit data to substantiate its claim on other complaints.

150. On December 14, 2006, the same day it denied the citizen petition, the FDA granted final approval Anchen's ANDAs.

151. On December 15, 2006, the FDA granted tentative approval to Impax for its 150mg bupropion hydrochloride extended release and final approval of its 300mg product, following Anchen's waiver of its exclusivity in favor of Impax.

152. Approximately six months later, on June 13, 2007, the FDA granted final approval to Watson for its 300mg bupropion hydrochloride extended release product.

153. Defendants' illegal conduct effectively delayed the market entry of generic bupropion HCl extended release. Defendants were aware of the FDA's practice of withholding ANDA approval until after its consideration of and response to a citizen petition was complete. Had Defendants not filed the sham citizen petition, Anchen would have received final approval earlier than it did.

154. On December 18, 2005, in response to the FDA's denial of Biovail's citizen petition and the FDA's concurrent approval of Anchen's application to market its generic substitute, Biovail filed a motion in an action previously brought *against the FDA* seeking an order to enjoin the effectiveness of the FDA's approval of Anchen's application, thereby preventing the launch of generic versions of Wellbutrin XL. In denying the motion, the court ruled that "the public also has a well-recognized interest in 'receiving generic competition to brand name drugs as soon as is possible,' and a 'delay in the marketing of [the generic] drug could easily be against the public interest in reduced prices.'" *See Biovail Corp. v. U.S. Food*

and Drug Administration, Case No. 06-1487(RMU) (D. D.C. March 22, 2007) (attached as Exhibit I).

M. Biovail Entered into Settlements with the Generic Manufacturers that Further Prevented Generic Substitutes from Reaching the Market

155. Following the FDA's denial of the citizen petition and approval of Anchen's ANDA for bupropion hydrochloride extended release products, Anchen transferred its 180-day exclusivity period for the 300mg product to Impax, which, in partnership with Teva Pharmaceuticals, another generic manufacturer, launched its own generic bupropion hydrochloride extended release 300mg product.

156. On March 5, 2007, Biovail announced the settlement of the infringement actions against Anchen, Impax, and Watson. Under the settlement agreement, Biovail granted Anchen, Impax, and Teva an exclusive license to market a generic 300mg bupropion HCl extended release product during Anchen's 180-day exclusive marketing period, from December 13, 2006 to June 13, 2007, with Watson coming on market thereafter. On July 31, 2007, following settlement negotiations, Defendants also settled their action against Abrika.

157. Biovail entered these settlements even though only one of the actions had gone to summary judgment and the purported patents *did not expire until 2018*, thus underscoring the sham nature of the litigation that had delayed generic entry.

158. At the time, Impax's motion for summary judgment based on non-infringement was pending against Biovail.

159. While the settlement agreements permitted generic competition on the 300 mg bupropion hydrochloride extended release product, they barred the generic competitors from releasing their 150 mg bupropion hydrochloride extended release formulations until 2008. In addition, even after the agreements permitted Anchen / Teva to launch a 150mg formulation of

bupropion hydrochloride extended release, they barred Watson from doing so until six months later. As a result, through the settlement of the generic infringement litigation, Biovail continued to foreclose generic competition, resulting in overcharges in the market for bupropion hydrochloride extended release to purchasers.

VII. INTERSTATE COMMERCE

160. Defendants' efforts to monopolize and restrain competition in the market for bupropion hydrochloride extended release drugs bupropion hydrochloride extended release have substantially affected interstate and foreign commerce.

161. At all material times, Defendants manufactured, promoted, distributed, and sold substantial amounts of Wellbutrin XL in a continuous and uninterrupted flow of commerce across state and national lines and throughout the U.S.

162. At all material times, Defendants transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Wellbutrin XL.

163. In furtherance of their efforts to monopolize and restrain competition in the market for bupropion hydrochloride extended release, Defendants employed the U.S. mails and interstate and international telephone lines, as well as means of interstate and international travel. Defendants' activities were within the flow of and have substantially affected interstate commerce.

VIII. MONOPOLY POWER AND MARKET DEFINITIONS

164. At all relevant times, Defendants had monopoly power over Wellbutrin XL and its generic equivalents because they had the power to maintain the price of Wellbutrin XL at supracompetitive levels without losing substantial sales.

165. A small but significant, non-transitory price increase by Defendants of Wellbutrin XL would not have caused a significant loss of sales.

166. Wellbutrin XL does not exhibit significant, positive cross-elasticity of demand with respect to price, with any product other than AB-rated generic versions of Wellbutrin XL.

167. Because of, among other reasons, its use and dissolution profile, Wellbutrin XL is differentiated from all products other than AB-rated generic versions of Wellbutrin XL.

168. Defendants needed to control only Wellbutrin XL and its AB-rated generic equivalents, and no other products, in order to maintain the price of Wellbutrin XL profitably at supracompetitive prices. So while the market entry of a competing, AB-rated generic version of Wellbutrin XL would render Defendants unable to profitably maintain their current prices of Wellbutrin XL without losing substantial sales, the existence of or entry into the market of non-AB rated products to Wellbutrin XL would render Defendants so unable.

169. Defendants also sold Wellbutrin XL at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

170. Defendants have had, and exercised, the power to exclude competition to Wellbutrin XL.

171. Defendants at all relevant times enjoyed high barriers to entry with respect to Wellbutrin XL.

172. To the extent that Plaintiffs are legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant market is all bupropion hydrochloride extended release products – *i.e.*, Wellbutrin XL (in all its forms and dosage strengths) and AB-rated bioequivalent bupropion hydrochloride extended

release products. During the period relevant to this case, Defendants have been able to profitably maintain the price of Wellbutrin XL well above competitive levels.

173. The relevant geographic market is the United States and its territories.

174. Defendants' market share in the relevant market was 100% at all times.

IX. MARKET EFFECTS

175. The acts and practices of Defendants had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Wellbutrin XL from generic competition. Defendants' actions allowed Defendants to maintain a monopoly and exclude competition in the market for bupropion hydrochloride extended release, to the detriment of all persons who paid for bupropion HCl extended release.

176. Through their anticompetitive conduct, Defendants have caused end payors to pay overcharges for bupropion hydrochloride extended release.

177. During the Class Period, Defendants' bupropion hydrochloride extended release products were the only such products commercially available in the United States. Even after generic bupropion hydrochloride extended release products became available, the unlawful acts and practices of Defendants continued to cause end payors to pay overcharges for bupropion hydrochloride extended release.

178. The manufacturers of generic bupropion hydrochloride extended release products invested a significant amount of time, effort, and resources in developing these products, and preparing and filing their ANDAs to enter the bupropion hydrochloride extended release market upon final FDA approval of their ANDAs. When the generic manufacturers filed their ANDAs, they intended to and were ready, willing and able to enter the bupropion HCl extended release market upon final FDA approval of their ANDAs. But for Defendants' misconduct, this would have occurred no later than November 14, 2005.

179. Had manufacturers of generic bupropion hydrochloride extended release products been able to enter the market and compete with Defendants, Plaintiffs and the End Payor Class members would have substituted lower-priced generic bupropion HCl extended release for the higher-priced brand name Wellbutrin XL for some or all of its bupropion HCl extended release requirements, and would have paid lower prices for its remaining Wellbutrin XL purchases.

180. During the Class Period, Plaintiffs and the End Payor Class members paid for substantial amounts of Wellbutrin XL. As a result of Defendants' illegal conduct, Plaintiffs and the End Payor Class members were compelled to pay, and did pay, artificially inflated prices for their bupropion hydrochloride extended release requirements. By preventing generic competitors from entering the market, Defendants injured Plaintiffs and the End Payor Class members in their business or property by causing them to pay more for Wellbutrin XL than they otherwise would have paid. Defendants' unlawful conduct deprived Plaintiffs and the End Payor Class members of the benefits of competition that the antitrust laws are intended to promote and preserve.

X. ANTITRUST IMPACT

181. During the Class Period, Plaintiffs and the End Payor Class members paid for substantial amounts of Wellbutrin XL. As a result of Defendants' illegal conduct, Plaintiffs and the End Payor Class members were compelled to pay artificially inflated prices for extended-release bupropion HCl. The prices Plaintiffs and the End Payor Class members paid were substantially greater than the prices they would have paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Wellbutrin XL was artificially inflated by Defendants' illegal conduct; and/or (2) End Payor Class members were deprived of the opportunity to pay for lower-priced generic versions of Wellbutrin XL sooner.

182. As a consequence, Plaintiffs and the End Payor Class members have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

XI. CLASS ACTION ALLEGATIONS

183. Plaintiffs, on their own behalf and on behalf of the End Payor Class defined below, seek monetary, equitable, injunctive and declaratory relief against Defendants based on allegations of anticompetitive conduct in the market for Wellbutrin XL and AB-rated generic equivalents.

184. Plaintiffs bring this consolidated action under Fed. R. Civ. P. 23(a), (b)(2) and (b)(3), as representatives of the following End Payor Class:

> All persons or entities who purchased an AB-rated generic bioequivalent of Wellbutrin XL ("generic XL") at any time during the "Class Period" (as hereafter defined) and all entities that purchased 150 mg or 300 mg Wellbutrin XL before an AB-rated generic bioequivalent was available for such dosages, and resided or had their place of business, or purchased the drug in California, Florida, Nevada, New York, Tennessee and Wisconsin. For purposes of the Class definition, persons and entities purchased Wellbutrin XL or generic XL if they paid some or all of the retail purchase price.
>
> Excluded from the Class are "flat co-payers" meaning natural persons whose only purchases of generic XL were made pursuant to contracts with third party payers ("TPP") whereby the amount paid by the natural person for generic XL was the same regardless of the retail purchase price.
>
> The Class Period begins November 14, 2005 and ends on the earlier of the date of judgment or the date (to be determined) when the price of generic XL reached or reaches "steady state," *i.e.* the price was no longer higher than it would have been on that date but for the delayed availability of generic XL caused by Defendants' alleged illegal conduct.

185. Excluded from the End Payor Class are: Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities and any person

or entity that purchased Wellbutrin XL and AB-rated generic equivalents in any form directly from Defendants.

186. Injunctive relief is appropriate under Rule 23(b)(2) because, as alleged herein, Defendants have acted on grounds generally applicable to the End Payor Class, thereby making appropriate final injunctive relief with respect to the End Payor Class as a whole.

187. Members of the End Payor Class are so numerous that joinder is impracticable. Plaintiffs believe that there are thousands of members of the End Payor Class.

188. Plaintiffs' claims are typical of the claims of the members of the End Payor Class. Plaintiffs and the End Payor Class members were damaged by the same wrongful conduct of Defendants, *i.e.*, they paid artificially inflated prices for bupropion HCl extended release and were deprived of the benefits of competition from cheaper generic versions of Wellbutrin XL as a result of Defendants' wrongful conduct.

189. Plaintiffs will fairly and adequately protect and represent the interests of the End Payor Class. The interests of the Plaintiffs are coincident with, and not antagonistic to, those of the End Payor Class.

190. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation involving pharmaceutical products.

191. Questions of law and fact common to the members of the End Payor Class predominate over questions that may affect only individual members because Defendants have acted on grounds generally applicable to the End Payor Class thereby making monetary and equitable relief with respect to the End Payor Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

192. Questions of law and fact common to the End Payor Class include:

(a) whether Defendants willfully obtained and/or maintained monopoly power over Wellbutrin XL and its generic equivalents;

(b) whether Defendants improperly listed the '327 patent in the Orange Book;

(c) whether Defendants' multiple actions asserting infringement of the '341 and '327 patents and seeking additional FDA review were baseless;

(d) whether Defendants engaged in sham litigation to prevent competition;

(e) whether Defendants filed their citizen petition to prevent competition;

(f) whether Defendants unlawfully excluded competitors and potential competitors from the market for Wellbutrin XL and AB-rated generic bioequivalents; and

(g) whether the Patent Litigation was objectively baseless;

(h) whether Defendants unlawfully delayed or prevented generic manufacturers from coming to market in the United States;

(i) whether Defendants maintained monopoly power by delaying generic entry;

(j) whether the law requires definition of relevant market when direct proof of monopoly power is available, and if so the definition of the relevant market;

(k) whether the activities of Defendants as alleged herein has substantially affected interstate commerce;

(l) whether and to what extent, Defendants' conduct caused antitrust injury (*i.e.,* overcharges) to Plaintiffs and the members of the End Payor Class; and

(m) the quantum of aggregate overcharge damages to the End Payor Class.

193. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class action mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

194. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

XII. CLAIMS FOR RELIEF

COUNT I

MONOPOLIZATION UNDER STATE LAW

195. Plaintiffs re-allege the preceding paragraphs as though set forth herein.

196. At all relevant times, Defendants have had monopoly power in the market for bupropion HCl extended release products.

197. Defendants used various illegal and deceptive means as part of an overall scheme to improperly extend patent protection for Wellbutrin XL by wrongfully manipulating the Hatch-Waxman statutory scheme, and to abuse the monopoly power created thereby. Defendants accomplished this scheme by, among other things: (a) wrongfully listing the '327 patent in the

Orange Book; (b) wrongfully conducting baseless litigation to trigger the automatic 30-month stay prohibiting the FDA from granting final approval permitting the ANDA filers to market their less-expensive generic bupropion HCl extended release; (c) wrongfully filing a citizen petition with the FDA in an attempt to delay generic versions of Wellbutrin XL from entering the market and pursuing litigation concerning the citizen petition; and (d) wrongfully entering into agreements with competitors to forestall generic competition.

198. The purpose and effect of Defendants' scheme was to exclude generic competition from the bupropion HCl extended release market in order to maintain market power in the market for generic bupropion HCl extended release, charge supracompetitive prices, and reap unlawful monopoly profits.

199. Defendants' acts of monopolization were undertaken with specific intent to monopolize the market for bupropion HCl extended release.

200. Plaintiffs and members of the End Payor Class paid for substantial amounts of bupropion HCl extended release.

201. The injury to Plaintiffs and the End Payor Class is the type of injury state antitrust laws were designed to prevent, and the injury flows from Defendants' unlawful conduct.

202. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant market in violation of Cal. Bus. & Prof. Code §§16700, *et seq.*, and Cal. Bus. & Prof. Code §§17200, *et seq.* with respect to purchases of Wellbutrin XL in California by members of the Class.

203. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant market in violation of Nev. Rev. Stat. Ann. §§598A, *et seq.*, with respect to purchases of Wellbutrin XL in Nevada by members of the Class.

204. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant market in violation of New York's Donnelly Act, N.Y. Gen. Bus. Law §§340, *et seq.*, with respect to purchases of Wellbutrin XL in New York by members of the Class.

205. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant market in violation of Tenn. Code Ann. §§47-25-101, *et seq.*, with respect to purchases of Wellbutrin XL in Tennessee by members of the Class.

206. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant market in violation of Wis. Stat §133.01, *et seq.*, with respect to purchases of Wellbutrin XL in Wisconsin by members of the Class.

207. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Count. Their injury consists of paying higher prices for Wellbutrin XL prescription drugs than they would have paid in the absence of those violations. This injury is of the type the antitrust and consumer protection laws of the above States and the District of Columbia were designed to prevent and flows from that which makes Defendants' conduct unlawful.

208. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by defendants' violations of the aforementioned statutes.

COUNT II

UNFAIR AND DECEPTIVE TRADE PRACTICES UNDER STATE LAW

209. Plaintiffs re-allege the preceding paragraphs as though set forth herein.

210. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below when they (a) wrongfully listed the '327 patent in the Orange Book; (b) wrongfully conducted baseless litigation to trigger the automatic 30-month stay prohibiting the FDA from granting

final approval permitting the ANDA filers to market their less-expensive generic bupropion HCl extended release; (c) wrongfully filed a citizen petition with the FDA in an attempt to delay generic versions of Wellbutrin XL from entering the market and pursuing litigation concerning the citizen petition; and (d) wrongfully entered into agreements with competitors to forestall generic competition. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs and class members were deprived of the opportunity to purchase a generic version of Wellbutrin XL and were forced to pay higher prices for bupropion HCl extended release from November 14, 2005 to the present.

211. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code §17200, *et seq.*

212. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. §501.201, *et seq.*

213. Plaintiffs and members of the Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair or deceptive acts alleged in this Count. Their injury consists of paying higher prices for Wellbutrin XL prescription drugs than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

XIII. PRESERVATION OF CLAIMS FROM PLAINTIFFS' FIRST AMENDED CONSOLIDATED CLASS ACTION COMPLAINT

214. Plaintiffs and Plaintiffs whose claims were previously dismissed, Mechanical Contractors-United Association Local 119 Health and Welfare Plan and Bricklayers and Masons Local Union No. 5 Ohio Health and Welfare Fund ("Dismissed Plaintiffs"), hereby preserve all claims and supporting allegations they made in their First Amended Consolidated Class Action

Complaint, dated March 26, 2009 [Docket No. 70] ("FAC"). *See U.S. ex rel. Atkinson v. P.A. Shipbuilding Co.*, 473 F.3d 506, 517 (3d Cir. 2007). For such purposes, Plaintiffs and Dismissed Plaintiffs hereby adopt by reference the claims and supporting allegations set forth in the FAC pursuant to Fed. R. Civ. P. 10(c).

XIV. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs, on behalf of themselves and the End Payor Class, respectfully pray that the Court:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a), (b)(2) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2) be given to the Class and declare the Plaintiffs as the representative of the End Payor Class;

B. Enter joint and several judgments against Defendants in favor of Plaintiffs and the End Payor Class;

C. Adjudge and decree the acts alleged herein, pursuant to Fed. R. Civ. P. 57 and 18 U.S.C. §2201(a), to be in violation of the state laws identified above;

D. Award the Class actual damages and multiple damages or punitive damages where available by law in an amount to be determined at trial;

E. Permanently enjoin the Defendants from continuing their unlawful conduct, so as to assure that similar anticompetitive conduct does not occur in the future;

F. Award Plaintiffs and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

G. Grant any such other further relief to which Plaintiffs may be entitled and/or is necessary to correct the anticompetitive effects caused by the unlawful conduct of Defendants and as the Court deems just and/or equitable.

XV. JURY DEMAND

Plaintiffs demand a trial by jury.

Dated: January 7, 2011

Respectfully submitted,

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& HART, P.C.

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CERTIFICATE OF SERVICE

I, Yolanda Rivera, hereby certify that on January 7, 2011, I caused the foregoing ***Second Amended Consolidated Class Action Complaint and Jury Demand for End Payors*** to be filed through the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

/s/Yolanda Rivera